IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
AT CLARKSBURG

REGENERON PHARMACEUTICALS, INC., Plaintiff, v. MYLAN PHARMACEUTICALS INC. and BIOCON BIOLOGICS INC. Defendants.	Case No. 1:22-cv-00061-TSK

DEFENDANTS' MOTION TO EXCLUDE EXPERT DEPOSITION TESTIMONY OF DRS. ALAN RYDER AND STEPHEN R. RUSSELL

Defendants Mylan Pharmaceuticals Inc. ("Mylan") and Biocon Biologics Inc. ("Biocon") move to exclude at trial the use by Plaintiff Regeneron Pharmaceuticals, Inc. ("Regeneron") of deposition testimony from Mylan's expert witnesses Dr. Alan Ryder and Dr. Stephen R. Russell, neither of whom are offering expert opinions at trial. Mylan retained Dr. Ryder to offer opinions regarding U.S. Patent No. 11,104,715 ("'715 patent"), which Regeneron stipulated as not infringed, and thus is not at issue for trial. Regeneron however seeks to offer portions of Dr. Ryder's deposition testimony for issues related to U.S. Patent No. 11,084,865 ("'865 patent"), despite Dr. Ryder never reviewing, considering, or disclosing it in connection with his expert reports. Relatedly, Mylan retained Dr. Russell to offer rebuttal opinions solely relating to the limited issue of non-infringement of U.S. Patent Nos. 10,888,601 ("'601 patent") and 11,253,572 ("'572 patent"). Dr. Russell was subsequently withdrawn from Defendants' witness list and he has not (and will not) offer live testimony at trial. Yet, at his deposition, Regeneron sought testimony on issues entirely outside the scope of Dr. Russel's properly disclosed Rule 26 opinions and foundational knowledge, including with respect to prior art references identified by Dr. Albini.

Regeneron's deposition designations of Drs. Ryder and Russell are irrelevant, will confuse the issues, and constitute hearsay to which there is no valid hearsay exception. Regeneron's deposition designations for Drs. Ryder and Russell should be excluded.

I. LEGAL STANDARDS.

The Fourth Circuit requires that the district court assess whether an expert's testimony is "relevant." *United States v. Smith*, 919 F.3d 825, 835 (4th Cir. 2019). "[R]elevance . . . is a precondition for the admissibility of expert testimony, in that the rules of evidence require expert opinions to assist the 'trier of fact to determine a fact in issue.'" *United States v. Ancient Coin Collectors Guild*, 899 F.3d 295, 318 (4th Cir. 2018) (quoting *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591 (1993)). Under the Federal Rules, evidence is not relevant if it has no tendency to make a fact at issue more or less probable than without the evidence or if the fact is not of consequence in determining the action, FED. R. EVID. 401, and "[i]rrelevant evidence is not admissible," FED. R. EVID. 402. Moreover, "[t]he court may exclude relevant evidence if its probative value is substantially outweighed by a danger of . . . unfair prejudice [and] confusing the issues." FED. R. EVID. 403.

"Where an expert witness is withdrawn prior to trial . . . the prior deposition testimony of that witness may not be used. That deposition testimony is hearsay." *Glendale Fed. Bank, FSB v. United States*, 39 Fed. Cl. 422, 425 (Fed. Cl. 1997); *see also Kirksey v. Schindler Elevator Corp.*, No. 15-0115, 2016 WL 7116223, at *16-17 (S.D. Ala. Dec. 6, 2016). An opposing party's expert's deposition testimony is not admissible unless it "was made by the party's agent or employee" or "was made by a person whom the party authorized to make a statement on the subject." *See 5N Techs. LLC v. Cap. One N.A.*, 56 F. Supp. 3d 755, 765 (E.D. Va. 2014) (citing FED. R. EVID. 801(d)(2)); *Skyhook Wireless, Inc. v. Google, Inc.*, No. 10-11571, 2015 WL 10015295, at *5 (D.

Mass. Feb. 27, 2015) ("Because [the opposing party] withdrew [the expert] before the trial … [the expert's] report and deposition are not party admissions by [the opposing party].").

II. THE DESIGNATED DEPOSITION TESTIMONY IS INADMISSIBLE HEARSAY.

Dr. Ryder's and Dr. Russell's deposition testimony (out-of-court statements Regeneron plans to offer to prove the truth of the matter asserted) should be excluded as inadmissible hearsay, which does not qualify for any exception.[1]

A. Dr. Ryder

Mylan proffered Dr. Ryder as an expert regarding non-infringement of the '715 patent and he submitted opinions limited to that subject matter. *Regeneron* (not Defendants) dropped the '715 patent from this case, rendering Dr. Ryder's opinions moot; hence, Dr. Ryder will not testify at trial. (*See* Dkt. No. 433 (conceding non-infringement)). Dr. Ryder's deposition testimony (which was procured subject to his now-moot report regarding the '715 patent) does not (and cannot) constitute an admission against Mylan regarding the unrelated '865 patent.

Although Federal Rule of Evidence 801(d)(2) creates a hearsay exception for either a person "authorized to make a statement on ***the subject*** " or a "party's agent or employee on a matter within the scope of that relationship," FED. R. EVID. 801(d)(2)(C)-(D) (emphasis added),

[1] Regeneron's prior arguments that Federal Rule of Civil Procedure 32(a) is an independent exception to the hearsay rules under the Federal Rules of Evidence are misplaced. (*See* Dkt. No. 492 at 2-3). Rule 32(a) provides that a deposition may be used only to the extent that use "***would be admissible*** under the Federal Rules of Evidence ***if the deponent were present and testifying***." Fed. R. Civ. P. 32(a)(1)(B) (emphasis added). Here, Regeneron seeks to elicit testimony that exceeds the scope of the experts' reports and, therefore, is outside the scope of any admissible cross-examination. *See* Fed. R. Civ. P. 26(a)(2)(B); Fed. R. Evid. 611(b). Further, Rule 32(a) does not provide an automatic requirement for the admission of deposition testimony, and, in fact, the Court may consider surprise to opposing counsel in deciding whether to admit that testimony. *Polys v. Trans-Colorado Airlines*, 941 F.2d 1404, 1410 (10th Cir. 1991). Here, the Court cautioned the parties that there should not be "any sabotages or surprises" at trial. (Dkt. No. 517, Pretrial Conf. at 72:19-20). Allowing Regeneron to present deposition testimony of experts directed to issues to which they were not retained and offered no written opinions is an unfair surprise to Mylan warranting the exclusion of that testimony.

Dr. Ryder was neither authorized to discuss the '865 patent, nor is he an agent or employee of Mylan. Dr. Ryder thus cannot "be authorized to make an admission for [Mylan]." *Kirk v. Raymark Indus., Inc.*, 61 F.3d 147, 164 (3d Cir. 1995). Therefore, his deposition testimony is inadmissible hearsay and should be excluded. *See 5N Technologies*, 56 F. Supp. 3d at 765; *see also Minebea Co. v. Papst*, No. 97-0590 (PLF), 2005 WL 6271045, at *1 (D.D.C. Aug. 2, 2005) ("Because, therefore, Minebea withdrew Mr. Wagner as an expert witness prior to trial, his deposition testimony will not be treated as an admission by a party-opponent and is therefore hearsay.")

B. Dr. Russell

Dr. Russell was proffered as an expert solely to provide non-infringement opinions for the '601 and '572 patents and he has since been withdrawn as a witness at trial. Regeneron therefore cannot rely on Dr. Russell's deposition testimony (which was procured subject to his now-moot report regarding non-infringement) as an admission against Mylan regarding unrelated invalidity issues. Moreover, Dr. Russell was neither authorized to opine on invalidity of the '601 and '572 patents, nor is he an agent or employee of Mylan. He therefore cannot "be authorized to make an admission for [Mylan]," which renders his deposition testimony inadmissible hearsay to which no exception applies. *Kirk*, 61 F.3d at 164; *see 5N Technologies*, 56 F. Supp. 3d at 765; *see also Minebea*, 2005 WL 6271045, at *1.

III. THE DESIGNATED DEPOSITION TESTIMONY IS IRRELEVANT.

The designated deposition testimony concerns topics that neither Dr. Ryder nor Dr. Russell considered or disclosed in their respective reports. That testimony is therefore irrelevant, and would serve no useful purpose other than to confuse the issues.

A. Dr. Ryder

During expert discovery, Dr. Ryder served as Mylan's expert witness regarding the '715 patent, and provided expert opinions pertaining to chemically defined media cell culture methods

which are non-infringement issues unique to the '715 patent. On April 19, 2023, this Court issued its Opinion and Order on Claim Construction (Dkt. No. 427), which confirmed that the M710 BLA manufacturing process does not and cannot infringe the '715 patent. Accordingly, Regeneron stipulated to non-infringement, and withdrew the '715 patent, (Dkt. No. 433), prompting Mylan to not include Dr. Ryder on its trial witness list provided to Regeneron on May 2, 2023, (Dkt. No. 452-1, Mylan Witness List). Despite the '715 patent being dropped, on May 5, 2023, Regeneron designated deposition testimony from Dr. Ryder regarding issues related to another patent that Dr. Ryder neither considered nor offered a written opinion on in this matter.

Dr. Ryder's designated deposition testimony is not relevant to the remaining asserted patents, in particular the '865 patent. At his deposition, Regeneron questioned Dr. Ryder about size exclusion chromatography ("SEC") testing and lyophilization methods for protein formulations—questions *only* relevant to the '865 patent in this case—knowing Dr. Ryder (i) never reviewed the '865 patent or referenced it in his report, (ii) never reviewed any of the underlying documents to offer opinions regarding the '865 patent, and, most notably, (iii) was never asked by Mylan to opine on SEC and/or how it relates to the '865 patent. Dr. Ryder testified accordingly, emphasizing (*multiple times*) that he had not been asked to comment on the '865 patent or to review related documents. (Dkt. No. 452-2, Ryder Tr. at 21:8-14, 22:2-23:7, 24:9-17, 25:5-12, 26:9-17).

Dr. Ryder also repeatedly testified that he did not personally conduct the SEC testing referenced in the 2020 publication that was the subject of the deposition questioning; that the work was done by other researchers. (Dkt. No. 452-2, Ryder Tr. at 11:2-12:5, 12:14-12:19). Moreover, when asked about his knowledge of SEC in 2006 (which Regeneron argues is the relevant timeframe), Dr. Ryder stated: "I cannot at the moment recollect, because I would have to go and check the status of the references and the quality of those references going back to 2006. I cannot

say, for a definitive, that in 2006, it was an accepted method. I just cannot remember specifics of the references that we would have consulted." (*Id.* at 16:3-17; *see also id.* at 19:4-12, 29:21-30:6). Dr. Ryder's testimony is not surprising because he was not proffered by Mylan as an expert in SEC, nor did he review relevant documents or offer opinions regarding SEC testing in 2006. Similarly, when asked about lyophilization (also subject matter that is unique to the '865 patent), Dr. Ryder indicated he did not have personal experience with the technique and that he had not been asked to consider (or offer an opinion regarding) it. (*Id.* at 31:3-16).

Given that Dr. Ryder had never reviewed the '865 patent and was being asked to provide testimony on matters he had not analyzed—and regarding a timeframe for which he did not have recollection of the relevant protocols—Dr. Ryder's deposition testimony is irrelevant and its use by Regeneron would not assist the trier of fact in assessing issues related to the '865 patent. *See, e.g.*, FED. R. EVID. 702; *Oglesby v. Gen. Motors Corp.*, 190 F.3d 244, 250-51 (4th Cir. 1999) ("[expert's] opinion lacked 'any probative value' because it lacked 'the reliability, foundation and relevance necessary for admissibility' under Federal Rule of Evidence 702"); *Perreira v. Dept. of Health & Hum. Servs.*, 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) ("An expert opinion is no better than the soundness of the reasons supporting it."). Moreover, the "probative value" of Dr. Ryder's testimony regarding subject matter he never considered—related to a patent he never reviewed—"is substantially outweighed by a danger of . . . unfair prejudice [and] confusing the issues," warranting exclusion under Federal Rule of Evidence 403 as well. FED. R. EVID. 403.

B. Dr. Russell

Dr. Russell properly disclosed opinions pursuant to FED. R. CIV. P 26, which were limited to non-infringement of the '601 and '572 patents, directed to methods of treating certain angiogenic eye disorders in a patient by administering aflibercept to that patient. Specifically, Dr.

Russell offered opinions regarding physician's prescribing and treatment practices for angiogenic retinal and choroidal disorders, confirming that biosimilar drug companies do not influence those practices. (*See, e.g.*, Dkt. No. 493-1, Russell Reb. ¶¶ 28-34, 60-62, 125-28). Dr. Russell offered those opinions in response to the infringement opinion by Regeneron's expert, Dr. Csaky, that physicians will rely on Mylan's proposed aflibercept biosimilar in their treatment decisions. (*Id.* ¶ 28, n.2). Dr. Russell did not disclose nor discuss issues relating to the invalidity of the '601 or '572 patents in his expert report.

Because Dr. Russell's opinion was limited to non-infringement of the '601 and '572 patents, Mylan retained other experts to opine on invalidity issues related to those patents, including Dr. Albini, whose testimony was presented to the Court on June 15, 2023. Mylan does not intend to call Dr. Russell at trial, a fact Regeneron has known since May 26, 2023, giving Regeneron ample opportunity to prepare an appropriate cross examination of Dr. Albini. Although Dr. Russell has been withdrawn as a witness, and further in spite of the fact that he disclosed no expert opinions on invalidity, Regeneron designated deposition testimony attempting to elicit from Dr. Russell testimony relating to invalidity issues concerning the '601 and '572 patents for which Dr. Russell had not considered in advance of his deposition.

During deposition, Regeneron asked Dr. Russell questions related to Mylan's invalidity defenses that far exceed the scope of his expert opinion on non-infringement, and Dr. Russell made clear during his deposition that he was not offering any opinion regarding the validity of the '601 and '572 patents and he had not reviewed any materials regarding the invalidity of those patents. (Dkt. No. 469-3, Russell Tr. at 298:7-15).

While Dr. Russell had neither formed an opinion nor considered materials with respect to invalidity, he was asked in his deposition to provide testimony on subject matter he had not

analyzed. Accordingly, Dr. Russell's deposition testimony is irrelevant and its use by Regeneron would not assist the trier of fact in assessing issues related to invalidity of the '601 and '572 patents. *See, e.g.*, FED. R. EVID. 702; *Oglesby*, 190 F.3d at 250-51; *Perreira*, 33 F.3d at 1377 n.6. Moreover, Federal Rule of Evidence 403 also warrants exclusion as the "probative value" of Dr. Russell's testimony regarding subject matter he never considered or opined upon is "substantially outweighed by a danger of . . . unfair prejudice [and] confusing the issues." FED. R. EVID. 403.

IV. CONCLUSION.

For the reasons stated herein, Mylan requests the Court exclude Regeneron from presenting the deposition testimony of Dr. Alan Ryder and Dr. Stephen R. Russell at trial.

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CERTIFICATE OF SERVICE

I certify that on the 21st day of June 2023, I filed the foregoing "Defendants' Motion to Exclude Expert Deposition Testimony of Drs. Alan Ryder and Stephen R. Russell" with the Court's CM/ECF system, which will send notification of the same to all counsel of record.

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